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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.) 09/775,398
Applicant) Plass, et al.
Filed) January 31, 2001
TC/A.U.) 1634
Examiner) Carla J. Myers

Confirmation No. 7997

For.) DETECTION OF METHYLATED CpG RICH
SEQUENCES DIAGNOSTIC FOR MALIGNANT CELLS
Docket No.) 22727/04075
Customer No.) 24024

Rule 1.132 Declaration (In re Katz) of Dr. Christoph Plass

Dear Sir:

I, Christoph Plass, the inventor in the above-identified application, state as follows:

1. I am the sole inventor of the methods described and claimed in the above-identified patent application.

Frühwald (Genes, Chromosomes, & Cancer, September 13, 2000, volume 30, pages 38-47)

2. I, along with Michael C. Frühwald, M. Su O'Dorisio, Zunyan Dai, Laura J. Rush, Ralf Krahe, Dominic J. Smiraglia, Torsten Pietsch, and Sara H. Elsea, am a co-author of the paper entitled "Aberrant Hypermethylation of the Major Breakpoint Cluster Region in 17p11.2 Medulloblastomas but not Supratentorial PNETs."

3. The other individuals listed as authors did not discover or invent the methods described and claimed in the above-identified application. None of these individuals made a conceptual contribution to the inventions claimed in the present application.

4. At the time the described studies described were conducted:

- (a) D. J. Smiraglia, J. D., M. C. Frühwald and L. J. Rush were postdoctoral fellows in my laboratory and worked under my supervision. M. C. Frühwald also provided technical assistance and tissue samples. ;
- (b) M. S. O'Dorisio provided tissue samples;
- (c) Zunyan Dai was a graduate student in my laboratory, provided technical assistance, and conducted experiments under my supervision;
- (d) Ralf Krahe was a fellow faculty member at The Ohio State University, provided technical assistance, and conducted experiments under my supervision;
- (e) Torsten Pietsch, a colleague at another institution, provided cell lines; and
- (f) Sara H. Elsea, a colleague at another institution, provided clones used in the studies.

Frühwald (Abstract, Pediatric Oncology, June 2000)

5. I, along with Michael C. Frühwald, M. Su O'Dorisio, Zunyan Dai, and Fred Wright, am a co-author of the abstract entitled "Promoter Hypermethylation in Medulloblastomas: Aspects of Tumor Biology and Potential Clinical Utility."

6. The other individuals listed as authors did not discover or invent the methods described and claimed in the above-identified application. None of these individuals made a conceptual contribution to the inventions claimed in the present application.

7. At the time the described studies described were conducted:

- (a) M. C. Frühwald was a postdoctoral fellow in my laboratory and worked under my supervision. M. C. Frühwald also provided tissue samples;
- (b) M. S. O'Dorisio provided tissue samples;
- (c) Zunyan Dai was a graduate student in my laboratory, provided technical assistance, and conducted experiments under my supervision; and
- (d) Fred Wright was a statistician at The Ohio State University, and provided statistical analysis.

Dai (Abstract, Stone Lab Meeting, September 2000)

8. I, along with Zunyan Dai, Patrick Ross, Romola Gordon and Gregory A. Otterson, am a co-author of the abstract entitled "Identification of Hypermethylated CpG Islands in Non-Small Cell Lung Cancer and Related Aberrant Gene Transcription."

9. The other individuals listed as authors did not discover or invent the methods described and claimed in the above-identified application. None of these individuals made a conceptual contribution to the inventions claimed in the present application.

10. At the time the described studies described were conducted:

- (a) Zunyan Dai was a graduate student in my laboratory, provided technical assistance, and conducted experiments under my supervision;
- (d) Patrick Ross provided tumor samples;
- (e) Romola Gordon provided technical assistance and conducted experiments under my supervision; and
- (f) Gregory A. Otterson provided tumor samples.

Smiraglia (Abstract, Gordon Research Conference, February 2000)

11. I, along with J. Smiraglia, J. Szymanska, S Kraggerud, RA Lothe, and P Peltomaki, am a co-author of the abstract entitled "Testicular Germ Cell Tumors as a Model System to Study DNA Methylation."

12. The other individuals listed as authors did not discover or invent the methods described and claimed in the above-identified application. None of these individuals made a conceptual contribution to the inventions claimed in the present application.

13. At the time the described studies described were conducted:

- (a) D. J. Smiraglia was a postdoctoral fellow in my laboratory, provided technical assistance and worked under my supervision;
- (d) J. Szymanska was a post-doctoral fellow in my laboratory, provided technical assistance,

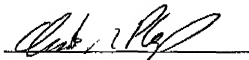
and conducted experiments under my supervision;

- (e) P Peltomaki was a fellow faculty member at The Ohio State University and provided tissue samples;
- (f) S Kraggerud was a post-doctoral fellow of Dr. Lothe, and provided tissue samples and technical assistance; and
- (g) RA Lothe, a colleague at another institution, provided tissue samples.

14. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

8/25/03

Date



Christoph Plass